

Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/IN05/000091

International filing date: 24 March 2005 (24.03.2005)

Document type: Certified copy of priority document

Document details: Country/Office: IN
Number: 364/MUM/2004
Filing date: 25 March 2004 (25.03.2004)

Date of receipt at the International Bureau: 16 August 2005 (16.08.2005)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)



World Intellectual Property Organization (WIPO) - Geneva, Switzerland
Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse

PCT / IN 05 / 00091



बौद्धिक सम्पदा भारत
INTELLECTUAL
PROPERTY INDIA
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सत्यमेव जयते

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THE PATENTS ACT, 1970

IT IS HEREBY CERTIFIED THAT, the annex is a true copy of the Application and Provisional Specification filed on 25/03/2004 in respect of Patent Application No.364/MUM/2004 of SUN PHARMACEUTICAL INDUSTRIES LTD., ACME PLAZA ANDHERI-KURLA ROAD, ANDHERI (E), MUMBAI - 400 059, MAHARASHTRA, INDIA, AN INDIAN COMPANY.

This certificate is issued under the powers vested in me under Section 147 (1) of the Patents Act, 1970.

Dated this 25th day of July 2005.

(RAKESH KUMAR)
ASSTT.CONTROLLER OF PATENTS & DESIGNS.

FORM 1

THE PATENTS ACT, 1970
(39 OF 1970)

APPLICATION FOR GRANT OF A PATENT
(See sections 5(2), 7, 54 and 135 and rule 33A)

We, SUN PHARMACEUTICAL INDUSTRIES LTD., ACME PLAZA, ANDHERI-KURLA ROAD, ANDHERI (E), MUMBAI-400059, MAHARASHTRA, INDIA

AN INDIAN COMPANY

hereby declare -

- (i) that we are in possession of an invention titled "**GASTRIC RETENTION DRUG DELIVERY SYSTEM**".
- (ii) that the provisional specification relating to this invention is filed with this application.
- (iii) that there is no lawful ground of objection to the grant of a patent to us.

We, further declare that the inventors for the said invention are
(1) DHARMADHIKARI, Nitin Bhalachandra; (2) ZALA, Yashoraj Rupsinh; both of SUN PHARMACEUTICAL ADVANCED RESEARCH CENTRE, 17/B Mahal Industrial Estate Off Mahakali Caves Road, Andheri (E), Mumbai 400093, Maharashtra, India; all Indian nationals.

We claim the priority from the applications filed in convention countries, particulars of which are as follows: Not Applicable

We state that the said invention is an improvement in or modification of the invention, the particulars of which are as follows and of which we are the applicant: Not Applicable

We state that the application is divided out of our application, the particular of which are given below and pray that this application deemed to have been filed under section 16 of the Act: Not Applicable

That we are the assignee of the true and first inventors.

That our address for service in India is as follows-

Dr. RATNESH SHRIVASTAVA,
INTELLECTUAL PROPERTY CELL,
SUN PHARMACEUTICAL INDUSTRIES LTD,
ACME PLAZA, ANDHERI-KURLA ROAD,
ANDHERI (E), MUMBAI-400 059, MAHARASHTRA, INDIA,
TELEPHONE NO-28397632, FACSIMILE NO- 28212010.

364/mum/2004
25/3/2004

364 | मुंबई | 2004
MUM

25 MAR 2004

30/03/04
25/3/04
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ORIGINAL

Following declaration was given by the inventors-
We, the true and first inventors for this invention declare that the applicant herein is our assignee.

Dated this 24th day of March, 2004

(Signatures) 1. _____
DHARMADHIKARI, Nitin Bhalachandra
2. _____
ZALA, Yashoraj Rupsinh

That to the best of our knowledge, information and belief, the fact and matters stated herein are correct and that there is no lawful ground of objection to the grant of a patent to us on this application.

Following are the attachment with the application:

- 1) Provisional specification (3 copies)
- 2) Fee Rs. 3000 in cheque bearing No. 435138 dated Nov 21, 2003 drawn on ICICI Bank Limited.

We request that a patent may be granted to us for the said invention

Dated this 24th day of March, 2004.

(Signature) _____

DILIP SHANGHVI
CHAIRMAN AND MANAGING DIRECTOR
SUN PHARMACEUTICAL INDUSTRIES LTD.

To
The Controller of Patents,
The Patent Office,
Mumbai - 400 013.

FORM 2

THE PATENTS ACT, 1970
(39 OF 1970)

PROVISIONAL SPECIFICATION
(See section 10)

GASTRIC RETENTION DRUG DELIVERY SYSTEM

SUN PHARMACEUTICAL INDUSTRIES LTD.

A company incorporated under the laws of India having their office at ACME PLAZA,
ANDHERI-KURLA ROAD, ANDHERI (E), MUMBAI-400059, MAHARASHTRA,
INDIA.

The following specification describes the nature of this invention.

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ORIGINAL

GASTRIC RETENTION DRUG DELIVERY SYSTEM

The present invention relates to a novel gastric retention drug delivery system.

The present invention provides a gastric retention drug delivery system capable of swelling and achieving floatation rapidly while maintaining its physical integrity in gastrointestinal fluids, the system comprising –

- (a) a therapeutically active ingredient,
- (b) a core comprising at least one pharmaceutically acceptable excipient,
- (c) a coat comprising at least one pharmaceutically acceptable excipient,

wherein the coat does not disintegrate rapidly upon contact with an aqueous fluid.

One embodiment of the present invention provides a gastric retention drug delivery system capable of swelling and achieving floatation rapidly while maintaining its physical integrity in gastrointestinal fluids, the system comprising –

- (i) a core comprising a therapeutically active ingredient, and
- (ii) a coat capable of expansion upon contact with an aqueous fluid,

wherein at least one dimension of the system is at least 5mm.

Another embodiment of the present invention provides a gastric retention drug delivery system capable of swelling and achieving floatation rapidly while maintaining its physical integrity in gastrointestinal fluids, the system comprising –

- (i) a core capable of expansion and comprising a therapeutically active ingredient,
and
- (ii) a coat capable of expansion upon contact with an aqueous fluid,

wherein at least one dimension of the system is at least 5mm.

The present invention also provides a gastric retention drug delivery system capable of swelling and achieving floatation rapidly while maintaining its physical integrity in gastrointestinal fluids, the system comprising –

- (i) a core comprising a therapeutically active ingredient and a gas generating agent,
and
- (ii) a coat capable of expansion,

wherein at least one dimension of the system is at least 5mm.

The present invention further provides a gastric retention drug delivery system capable of swelling and achieving floatation rapidly while maintaining its physical integrity in gastrointestinal fluids, the system comprising –

- (i) a core capable of expansion and comprising a therapeutically active ingredient
and a gas generating agent, and
- (ii) a coat capable of expansion

wherein at least one dimension of the system is at least 5mm.

In one embodiment, the present invention also provides a gastric retention drug delivery system capable of swelling and achieving floatation rapidly while maintaining its physical integrity in gastrointestinal fluids, the system comprising –

- (i) a core comprising a therapeutically active ingredient and a gas generating agent,
and
- (ii) a coat surrounding the core,

wherein at least one dimension of the system is at least 5mm.

In another embodiment, the present invention also provides a gastric retention drug delivery system capable of swelling and achieving floatation rapidly while maintaining its physical integrity in gastrointestinal fluids, the system comprising –

- (i) a core comprising a therapeutically active ingredient and a gas generating agent,
and
- (ii) a coat surrounding the core, wherein the coat retards the diffusion of gas
generated in the core upon contact with an aqueous fluid, to the external
environment,

wherein at least one dimension of the system is at least 5mm.

One embodiment, the present invention provides a gastric retention drug delivery system capable of swelling and achieving floatation rapidly while maintaining its physical integrity in gastrointestinal fluids, the system comprising –

- (i) a core capable of expansion and comprising a therapeutically active ingredient and a gas generating agent, and
- (ii) a coat surrounding the core,

wherein at least one dimension of the system is at least 5mm.

Another embodiment, the present invention provides a gastric retention drug delivery system capable of swelling and achieving floatation rapidly while maintaining its physical integrity in gastrointestinal fluids, the system comprising –

- (i) a core comprising a therapeutically active ingredient and a gas generating agent, and
- (ii) a coat capable of expansion, surrounding the core,

wherein at least one dimension of the system is at least 5mm.

In yet another embodiment, the present invention provides a gastric retention drug delivery system capable of swelling and achieving floatation rapidly while maintaining its physical integrity in gastrointestinal fluids, the system comprising –

- (i) a core comprising a therapeutically active ingredient, and
- (ii) a coat comprising a gas generating agent,

wherein at least one dimension of the system is at least 5mm.

Another embodiment of the present invention provides a gastric retention drug delivery system capable of swelling and achieving floatation rapidly while maintaining its physical integrity in gastrointestinal fluids, the system comprising-

- (i) a core comprising a gas generating agent, and
- (ii) a coat comprising a therapeutically active ingredient.

wherein the gastric retention drug delivery system is a unit dosage form in which at least one of the dimensions is more than 5mm. and the unit dosage form is non-disintegrating in gastrointestinal fluids.

Yet another embodiment of the present invention provides a gastric retention drug delivery system capable of swelling and achieving floatation rapidly while maintaining its physical integrity in gastrointestinal fluids, the system comprising -

- (i) a core comprising a gas generating agent, and
- (ii) a coat comprising a therapeutically active ingredient, the coat capable of expansion,

wherein the gastric retention drug delivery system is a unit dosage form, in which at least one of the dimensions is more than 5mm, and the unit dosage form is non-disintegrating in gastrointestinal fluids.

One embodiment of the present invention provides a gastric retention drug delivery system capable of swelling and achieving floatation rapidly while maintaining its physical integrity in gastrointestinal fluids, the system comprising -

- (i) a core comprising a therapeutically active agent, a gas generating agent, and other pharmaceutically acceptable excipients,
- (ii) a coat capable of expansion, and
- (iii) optionally, a second outer coat capable of rapid swelling,

wherein at least one dimension of the system is at least 5mm.

Another embodiment of the present invention provides a gastric retention drug delivery system capable of swelling and achieving floatation rapidly while maintaining its physical integrity in gastrointestinal fluids, the system comprising -

- (i) a core comprising a therapeutically active agent, a gas generating agent, and other pharmaceutically acceptable excipients,
- (ii) a coat capable of expansion and comprising a gas generating agent, and
- (iii) optionally, a second outer coat capable of rapid swelling,

wherein at least one dimension of the system is at least 5mm.

The present invention provides gastric retention drug delivery system that is capable of providing controlled release or immediate release of the therapeutically active ingredient

contained therein. The core of the system may comprise pharmaceutically acceptable excipients known in the art and capable of controlling release of the therapeutically active ingredient.

The gas generating agent that may be used in the gastric retention drug delivery system of the present invention may include a single component that generates gas upon contact with the gastric fluids, or may include a gas generating couple. The gastric retention drug delivery system of the present invention may include the gas generating agent in the core, in the coat surrounding the core, in the second rapidly swelling coat, or in all of the above.

In one embodiment, the present invention provides a gastric retention drug delivery system capable of swelling and achieving floatation rapidly while maintaining its physical integrity in gastrointestinal fluids, the system comprising –

- (i) a core comprising a therapeutically active agent, a gas generating agent, a swelling agent and other pharmaceutically acceptable excipients,
- (ii) a coat capable of expansion and comprising a swellable polymer and a gas generating agent, and
- (iii) optionally, a second outer coat capable of rapid swelling, comprising a swelling agent.

Dated this 24th day of March, 2004.


DILIP SHANGHVI,

CHAIRMAN AND MANAGING DIRECTOR,
SUN PHARMACEUTICAL INDUSTRIES LIMITED.